

AMENDMENTS

In the Claims:

1-32. (canceled)

33. (Currently Amended) A pharmaceutical composition comprising recombinant human N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and a polyoxyethylenesorbitan.

34. (Currently Amended) A pharmaceutical composition comprising recombinant human N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and polyoxyethylenesorbitan 20 or 80.

35. (Currently Amended) A pharmaceutical composition comprising recombinant human N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and polyoxyethylenesorbitan 20.

36. (Currently Amended) A pharmaceutical composition comprising recombinant human N-acetylgalactosamine-4-sulfatase, a pharmaceutically acceptable carrier, and polyoxyethylenesorbitan 80.

37. (Previously Presented) The pharmaceutical composition of any one of claims 33 through 36, wherein said polyoxyethylenesorbitan concentration is about 0.001% (W/V).

38. (CANCELLED)

39. (CANCELLED)

40. (Previously Presented) A pharmaceutical composition suitable for administration to humans comprising recombinant human N-acetylgalactosamine-4-sulfatase and a pharmaceutically acceptable carrier, said composition having the following characteristics:

- (a) activity by fluorescence assay is between about 20,000 and 120,000 mUnits;
- (b) absence of detectable adventitious viruses;
- (c) absence of detectable mycoplasma;
- (d) endotoxin level by LAL assay of about 2 EU/mL or less;
- (e) about 600 or less particulates of 25 μ m in size per vial;
- (f) about 6000 or less particulates of 10 μ m in size per vial;

- (g) pH between about 5.5 and 6.8;
- (h) protein concentration of about 0.8 to 1.2 mg/mL;
- (i) one major band between about 65 and 70 kDa detectable on SDS-PAGE;
- (j) greater than about 95% purity by RP-HPLC; and
- (k) calculated specific activity of between about 40,000 and 80,000 mUnits per milligram of protein.

41. (Currently Amended) The pharmaceutical composition of claim 40 produced by a purification process comprising the steps of:

- (a) harvesting fluid obtained from a culture of cells transformed with a gene encoding a recombinant human N-acetylgalactosamine-4-sulfatase;
- (b) running the fluid on a DEAE sepharose column;
- (c) running the fluid on a Blue sepharose FF column;
- (d) running the fluid on a copper chelating sepharose column;
- (e) running the fluid on a phenyl sepharose column; and
- (f) diafiltering the purified recombinant human N-acetylgalactosamine-4-sulfatase.